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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/350,518	07/09/1999	JOHN C. REED	P-LJ-3578	8259

23601 7590 01/13/2003

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EXAMINER

HOLLERAN, ANNE L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/350,518

Applicant(s)

REED, JOHN C.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-14, 16, 20-27, 32-34, 36, 37, 44 and 50-61 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 11-14, 16, 20-27, 32-34, 36, 37, 44, and 50-61 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

### **DETAILED ACTION**

1. The amendment filed October 15, 2002 is acknowledged. Claims 11, 16, 25, 27, 32, 34 and 44 were amended. Claims 50-61 were added. (Please note that the amendment lists these claims as 45-56, however, these claims were renumbered as 50-61 according to 37 C.F.R. 1.126).

The "Remarks" section of the amendment indicates that claims 6-8, 18, 19, 29-31 and 35 are to be canceled.

Claims 11-14, 16, 20-27, 32-34, 36, 37, 44, and 50-61 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The declaration filed by Dr. Lloyd Hutchinson was considered.

#### ***Rejections Maintained:***

4. The rejection of claims 11-14, 16, 20-27, 32-34, 36, 37, 44, and 50-61 under 35 U.S.C. 112, first paragraph, is maintained and made for new claims 50-61.

For claims 16, 11-14, 20-24, 50, 54-57 the rejection is maintained on the grounds that the specification fails to enable methods where BAG-1 protein levels are measured in a body fluid. The declaration filed by Dr. Lloyd Hutchinson is not commensurate with the scope of the claims and fails to persuade. The declaration demonstrates that BAG-1 protein is measurable in urine or

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men with and without prostate cancer, but not that the measurement of BAG-1 protein levels in a body fluid correlates with the prognosis of a patient suffering from breast cancer (or for that matter, prostate cancer).

For claims 25, 26, 51, 58, and 44 and 61 the rejection is maintained for the reasons set forth for claims 16, 11-14, 20-24, 50, 54-57, above, and also because the specification fails to enable methods where measurement of BAG-1 protein is correlated with risk of tumor recurrence or spread. Applicant argues that tumor recurrence or spread is correlated with disease-free or overall survival. However, tumor recurrence or spread appear to be factors that contribute to the measurement of disease-free or overall survival, and correlation with these parameters does not necessarily predict that a correlation will be found for tumor recurrence or tumor spread.

For claims 27, 32, 33, 52 and 59 the rejection is maintained for the reasons set forth for claims 16, 11-14, 20-24, 50, 54-57.

For claims 34, 36, 37, 53 and 60 the rejection is maintained for the reasons set forth for claims 16, 11-14, 20-24, 50, 54-57, above, and also because the specification fails to teach which levels of BAG-1 expression allow the division into the two groups. The specification teaches that disease-free or overall survival is correlated with BAG-1 protein levels, but not how to determine the cut-off values of BAG-1 that would be necessary to divide a group of patients into two groups, each requiring separate treatments.

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***New Grounds of Rejection:***

5. Claims 11-14, 20, 21, 26, 32, 33, 36, 37, 44, 50-53, and 55-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 13, 14, 20, 21, 50, 55, 56, and 57 are indefinite because they lack antecedent basis in claim 16 for “said level of BAG-1 expression”, when claim 16 recites “level of BAG-1 protein expression”.

Claims 26, 51 and 58 are indefinite because they lack antecedent basis for “the level of BAG-1 expression” in claim 25.

Claims 32 and 33 are indefinite because they lack antecedent basis for “the amount of BAG-1 protein” in claim 27.

Claims 52 and 59 are indefinite because they lack antecedent basis for “said level of BAG-1 expression” in claim 27.

Claims 36, 37, 53 and 60 are indefinite because they lack antecedent basis for “said level of BAG-1 expression” in claim 34.

Claim 44 is indefinite because it lacks a recitation of the correlation between performance of the method steps and the purpose of the method that is stated in the preamble.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran

Patent Examiner

January 13, 2003

  
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